

REMARKS

Entry of the foregoing, reexamination and reconsideration of the above-identified application are respectfully requested.

Claim 11 has been amended to recite an "isolated" filamentous fungus.

Claims 8, 9, 38, 39, 53, 56, 57 and 70 have been amended to delete "artificial treatment" or "artificially treating" and instead recite that the microorganism is "subject to" "mutation, gene manipulation or cell fusion." Support for this amendment may be found at the very least at page 10, and in claims 50, 53 and 78, which claims have been cancelled accordingly.

Claim 11 has been rejected under 35 U.S.C. §101, as allegedly being directed to nonstatutory subject matter. This rejection is rendered moot by the instant amendment. The claim has been amended, as helpfully suggested by the Examiner, to recite that the claimed filamentous fungus is "isolated." The claim is thus now directed to statutory subject matter. Withdrawal of the rejection is respectfully requested.

Claims 1-14, 30-34, 36-43, 52-58 and 65-68 and 70-73 have been rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter not enabled by the specification. This rejection is respectfully traversed.

The claims are said to be directed to a composition obtained by culturing a microorganism, wherein the microorganism is *Mortierella alpina* strains IFO 8568 and mutants SAM 2241 and SAM 2242. The microorganisms are said to be essential to the invention and must be "obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public." A Supplemental Deposit Declaration was submitted on July 22, 2003. This deposit declaration should be acceptable and establish enablement for *Mortierella elongata* SAM 0219 and *Mortierella alpina* SAM 2241. With respect to IFO 8568, this strain is publically available from IFO, as described on page 10, lines 10-11 of the specification. For confirmation, enclosed is a copy of relevant pages from an IFO catalog. As can be seen from page 73 of the catalog, the strain IFO 8568 has been

stored since 1966, and is available to the public, as shown in the "Introduction" section on page (i). Regarding *Mortierella alpina* SAM 2242, this strain as well as strains having the same properties can be obtained according to the procedures described on pages 10-12, as well as Example 1 on pages 20-22. No undue experimentation would be necessary to prepare such microorganism strains. The specification clearly teaches one skilled in the art how to make the claimed strains and one skilled in the art could readily follow those instructions to obtain *Mortierella alpina* SAM 2242, and other strains having the same properties.

Withdrawal of this rejection is respectfully requested and believed to be in order.

Claims 1-14, 30-34, 36-43, 52-58, 65-68 and 70-73 have been rejected under 35 U.S.C. 112, first paragraph, as allegedly containing subject matter not enabled by the specification. This rejection is respectfully traversed.

While the specification is acknowledged to be enabling for *M. alpina* strains SAM 2241 and SAM 2242, it allegedly does not enable "any and all microorganisms which extracellularly secrete encapsulated lipid vesicles as claimed." According to the Examiner, "the art of mutation with respect to imparting particular characteristics/properties to such mutant strains is well known to be difficult and highly unpredictable," citing Demain et al, Manual of Industrial Microbiology and Biotechnology, 1986, American Society for Microbiology, page 188, Col. 2, lines 20-36. Thus, undue experimentation is asserted to be required to isolate/obtain a microorganism having the claimed characteristics other than the two specific strains exemplified, i.e., SAM 2241 and 2242.

It is respectfully asserted that no undue experimentation would be necessary for one skilled in the art to practice the invention as claimed. One skilled in the art could readily practice the claimed invention based upon information provided in the specification and available in the art. As noted on pages 9-10 of the specification, other microorganisms in addition to SAM 2241 and 2242 could be used. See, page 9, line 28 - page 10, line 9. As noted on page 10, lines 10-16, many of the strains provided in the application are available

without limitations from the IFO in Osaka, Japan, the ATCC in the United States, and CBS. The specification also describes how to obtain a microorganism according to the instantly claimed invention. For example, at page 10, line 32 to page 12, line 37, subjecting the microorganism, as recited in the claims, to mutation, gene manipulation or cell fusion is described. How to screen the treated microorganisms to determine which meet the limitations of the claims is also described. Example 1 at pages 20-22 similarly describes how to obtain a microorganism as claimed. One skilled in the art could thus practice the claimed invention based upon the information in the specification and publically available resources.

Withdrawal of this rejection is thus respectfully requested and believed to be in order.

Claims 8, 9, 38, 39, 53, 56, 57 and 70 have been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. This rejection is rendered moot by the instant amendment.

The phrase "artificially treating" or "artificial treatment" in claims 8, 9, 38, 39, 53, 56, 57 and 70 is said to be unclear and a definition of the phrases is requested. The claims have been amended to define, in accordance with the specification, the treatment as being "mutation, gene manipulation or cell fusion."

Claim 52 has been rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite. The phrase "DHA" in claim 52 allegedly renders the claim indefinite. This rejection is rendered moot by the instant amendment.

Claim 52 has been amended to write out "4,7,10,13,16,19-docosaheptaenoic acid (DHA)," as given on page 8 of the specification.

Withdrawal of this rejection of record is respectfully requested and believed to be in order.

Applicants note with appreciation the indication that all of the prior art rejections have been withdrawn.

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, a Notice of Allowance is respectfully requested.


In the event that there are any questions relating to this amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 836-6620 so that prosecution of the application may be expedited.

Respectfully submitted,

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Date: January 15, 2004

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INSTITUTE FOR FERMENTATION
OSAKA

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LIST OF CULTURES

1978

SIXTH EDITION

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1978

INSTITUTE FOR FERMENTATION, OSAKA

17-85, Juso-honmachi 2-chome, Yodogawa-ku, Osaka 532, Japan.

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The Institute for Fermentation, Osaka (IFO) Organization

Ever since early in the 20th century authentic cultures of microorganisms were collected and preserved in several national organizations in Japan. The FAT collection at the Department of Agricultural Chemistry, University of Tokyo, the CLMR collection at the Central Laboratory of the South Manchuria Railway Co., and the GRIF collection at the Government Research Institute of Formosa were noted for their achievement.

The IFO collection started in 1944 on the basis of the cultures derived from the GRIF and FAT collection and in 1946 the cultures from the CLMR collection were added through the courtesy of Professor Hirosuke Naganishi of Hiroshima University. The IFO collection was greatly indebted for its development to research organizations and culture collections in Japan and abroad, and its persisting activities to the generous support by Takeda Chemical Industries Ltd. The IFO is a unique private but open-to-public organization for collection, preservation and distribution of authentic cultures of microorganisms of importance to science and technology. The number of cultures maintained in this collection reached to nine thousands at the end of 1977.

Deposit of cultures

The IFO accepts for deposit cultures of the strains of newly described species and new strains of known species which have properties of special interest and are not listed in this catalogue. Workers wishing to deposit a strain should write to the curator giving relevant details. Before acceptance of strain a data sheet must be completed by the depositor. It should be sent to IFO with several lyophilized samples, if possible, and two copies of papers citing the strains. The living culture is accepted for the filamentous fungi to which lyophilization can not be applied. The IFO also accepts for deposit cultures which are subject of patent applications. Conditions for the deposit and distribution of the cultures varies according to national and international regulation. When a depositor requests the collection to maintain his strain with certain restriction, an annual fee is charged.

Preservation of cultures

The IFO cultures are maintained on solid media and in the lyophilized, L-dried* or parafin-sealed conditions. Most of the cultures are preserved in rooms regulated at 5 and 8 C.

Ordering cultures

Cultures are supplied to research and industrial laboratories, to hospitals and to educational establishment. The culture is supplied as lyophilized or L-dried specimen or a living culture on an agar slant. Bacteriophages are supplied as liquid suspension in a glass vial or L-dried specimen*. All orders and other correspondence should be addressed to

The Institute for Fermentation, Osaka

17-85 Juso-honmachi 2-chome, Yodogawaku, Osaka, 532, Japan.

The following charges are requested, the charge should be paid after the invoice is sent to the client:

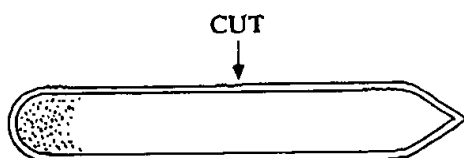
For non-profit organizations
For commercial firms

¥2,000 (Postages and handling charge extra)
¥5,000 (Postages and handling charge extra)

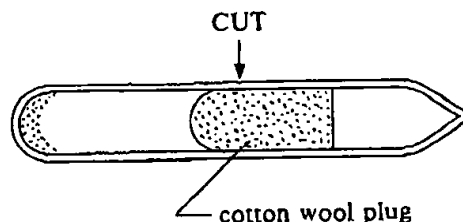
Thirty species are listed in the Appendix 1 as the reference cultures to high school education. In so far as organism in this list is concerned choice of strains should be left in charge of the curator. Culture fee is ¥500 per culture.

Reviving dried specimens

After sterilizing ampoule with alcohol-damped gauze, make a file cut on the ampoule at the mid-point of the cotton wool plug (in the case of L-dried specimens) or at the upper part of the tube (in the case of Lyophilized specimens), and apply a red hot glass rod to the file cut. Remove the pointed top part and then an appropriate medium was added into the ampoule aseptically, and the content was mixed (Notice: Rehydrate the sample at once). The suspension



Lyophilized Specimen



L-Dried Specimen

Mortierella alpina Peyronel	
8568 IFO (K. Tubaki; 1902-3).	1966
Mortierella astrogrisea van Beyma	
cf. <i>Mortierella isabellina</i>	
Mortierella bainieri Costantin	1966
8569 IFO (K. Tubaki; D-4-1).	
Mortierella elongata Linnemann	1966
8570 IFO (K. Tubaki; D-1-5).	
Mortierella exigua Linnemann	1966
8571 IFO (K. Tubaki; B-3-6).	
Mortierella humicola Oudemans	1964
8188 IFO (K. Tubaki; S-78-1).	1965
8288 IFO (K. Tubaki; S-6-1).	1965
8289 IFO (K. Tubaki; S-77-2).	
Mortierella hygrophila Linnemann	1954
5941 IMI 50115 --- M. Turner, 11 --- CBS.	
Mortierella isabellina Oudemans	1957
6336 (<i>Mortierella pusilla</i> var. <i>isabellina</i>). T. Kojiro, 2, soil.	1960
6739 (<i>Mortierella pusilla</i> var. <i>isabellina</i>). T. Kojiro, KN-133 --- NI 1186 (K. Tubaki; 87-2).	
7824 IFO (K. Tubaki; 87-2).	1963
7873 (<i>Mortierella astrogrisea</i>). CBS (F. H. van Beyma).	1963
7874 CBS --- H. Zycha.	1963
7884 (<i>Mortierella isabellina</i> var. <i>ramifica</i>). CBS --- E. I. McLennan.	1964
8183 IFO (K. Tubaki; S-104-2).	1965
8286 IFO (K. Tubaki; S-98-1).	1965
8308 IFO (K. Tubaki; S-37-2).	1965
8309 IFO (K. Tubaki; S-50-3).	1965
8572 IFO (K. Tubaki; 501-1).	1966
Mortierella isabellina Oudemans var. <i>ramifica</i> Dixon-Stewart	
cf. <i>Mortierella isabellina</i>	
Mortierella minutissima van Tieghem	1966
8573 IFO (K. Tubaki; B-5-7).	
Mortierella nana Linnemann	1964
8190 IFO (K. Tubaki; S-32-1).	1967
8794 CBS --- G. Linnemann.	1967
8795 CBS (E-110).	
Mortierella parvispora Linnemann	1966
8574 IFO (K. Tubaki; 406-2).	
Mortierella polycephala Coemans	1957
6335 T. Kojiro, 3, soil.	
Mortierella pusilla Oudemans var. <i>isabellina</i> (Oudemans) Zycha	
cf. <i>Mortierella isabellina</i>	
Mortierella pusilla Oudemans var. <i>vinacea</i> (Dixon-Stewart) Zycha	
cf. <i>Mortierella vinacea</i>	
Mortierella ramanniana (Möller) Linnemann	1963
7825 IFO (K. Tubaki; 86-13).	1964
8184 IFO (K. Tubaki; S-111-2).	1964
8185 IFO (K. Tubaki; S-121-3).	1965
8287 IFO (K. Tubaki; S-88-1).	
Mortierella ramanniana (Möller) Linnemann var. <i>angulispora</i> (Naumov) Linnemann	1952
5426 AHU (N. Nakane; N-17; forest soil).	1960
6744 (<i>Mucor angulisporus</i>). T. Kojiro, KN-4 --- NI 1065.	1964
8186 IFO (K. Tubaki; S-110-1).	1964
8187 IFO (K. Tubaki; S-3-1).	
Mortierella verticillata Linnemann	1966
8575 IFO (K. Tubaki; E-3-4).	
Mortierella vinacea Dixon-Stewart	